PRIOR AUTHORIZATION POLICY

POLICY: Neurology – Lyrica CR Prior Authorization Policy
- Lyrica® CR (pregabalin extended-release tablets – Pfizer, generic)

REVIEW DATE: 03/22/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Pregabalin extended-release tablets, an analog of gamma-aminobutyric acid (GABA), are indicated for the following uses:[1]
- **Neuropathic pain associated with diabetic peripheral neuropathy** (DPN), management in adults.
- **Postherpetic neuralgia** (PHN), management in adults.

The efficacy of pregabalin extended-release tablets has not been established for the management of fibromyalgia or as adjunctive therapy for adults with partial onset seizures.[1]

Gabapentin immediate-release (IR), an analog of GABA, is indicated for the following uses:[2]
- **Partial onset seizures**, with and without secondary generalization, as adjunctive therapy in adults and pediatric patients ≥ 3 years of age with epilepsy.
- **PHN**, management in adults.

Pregabalin IR capsules and oral solution are indicated for the following uses:[3]
- **Fibromyalgia**, management in adults.
- **Neuropathic pain associated with DPN**, management in adults.

- **Neuropathic pain associated with spinal cord injury**, management in adults.
- **Partial onset seizures**, as adjunctive therapy for the treatment in patients ≥ 1 month of age.
- **PHN**, management in adults.

Disease Overview

PHN is the persistence of the pain of herpes zoster > 3 months after resolution of the rash; it is relatively common, affecting 10% to 15% of those with herpes zoster.[4] Administration of antiviral agents within 72 hours of the onset of herpes zoster can reduce the intensity and duration of acute illness and can prevent PHN. Efforts to prevent herpes zoster and PHN are important because 40% to 50% of patients with PHN do not respond to any treatment.

The diabetic neuropathies are a heterogeneous group of disorders with diverse clinical manifestations.[5] The early recognition and appropriate management of neuropathy in the patient with diabetes is important. Up to 50% of DPN may be asymptomatic. Painful diabetic neuropathy affects 16% of patients with diabetes, and it is frequently unreported (12.5%) and more frequently untreated (39%).[6] If not recognized and if preventive foot care is not implemented, patients are at risk for injuries to their insensate feet.[5] Recognition and treatment of autonomic neuropathy may improve symptoms, reduce sequelae, and improve quality of life. Therapeutic strategies (pharmacologic and nonpharmacologic) for the relief of painful DPN can potentially reduce pain and improve quality of life.

Guidelines

Various guidelines for the treatment of DPN, neuropathic pain, PHN, and restless legs syndrome recommend gabapentin or pregabalin immediate-release as treatment options.[4-11] Guidelines do not address pregabalin extended-release tablets.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of pregabalin extended-release tablets. All approvals are provided for the duration noted below.

- **Lyrica® CR (pregabalin extended-release tablets (Pfizer, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Neuropathic Pain Associated with Diabetic Peripheral Neuropathy.** Approve pregabalin extended-release tablets for 1 year if the patient meets the following criteria (A and B):

A) Patient has tried gabapentin immediate-release (brand [Neurontin] or generic) or generic immediate-release pregabalin; AND
B) If brand Lyrica CR is requested, the patient meets BOTH of the following (i and ii):
   i. Patient has tried generic pregabalin extended-release tablets; AND
   ii. Patient cannot continue to use the generic due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

2. **Postherpetic Neuralgia.** Approve pregabalin extended-release tablets for 1 year if the patient meets the following criteria (A and B):
   A) Patient has tried gabapentin immediate-release (brand [Neurontin] or generic) or generic immediate-release pregabalin; AND
   B) If brand Lyrica CR is requested, the patient meets BOTH of the following (i and ii):
      i. Patient has tried generic pregabalin extended-release tablets; AND
      ii. Patient cannot continue to use the generic due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which, according to the prescriber, would result in a significant allergy or serious adverse reaction.

CONDITIONS NOT COVERED

- **Lyrica® CR (pregabalin extended-release tablets (Pfizer, generic)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Fibromyalgia.** A double-blind, placebo-controlled, randomized withdrawal trial of pregabalin extended-release tablets in adults with fibromyalgia failed to demonstrate efficacy.[1]

2. **Partial Onset Seizures.** A double-blind, placebo-controlled, randomized trial of pregabalin extended-release tablets as adjunctive therapy in adults with partial onset seizures failed to demonstrate efficacy.[1]

3. **Restless Legs Syndrome.** No data are available for pregabalin extended-release tablets for the treatment of restless legs at this time.

REFERENCES

1. Lyrica® CR extended-release tablets [prescribing information]. New York, NY: Pfizer; April 2020.

2. Neurontin® capsules, tablets, oral solution [prescribing information]. New York, NY: Pfizer; December 2020.
3. Lyrica capsules and oral solution [prescribing information]. New York, NY: Pfizer; April 2020.
4. Dubinsky RM, Kabbani H, El-Chami Z, et al. Practice parameter: treatment of postherpetic neuralgia: an evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2004;63(6):959-965.
5. American Diabetes Association Professional Practice Committee; 12. Retinopathy, Neuropathy, and Foot Care: *Standards of Medical Care in Diabetes—2023*. *Diabetes Care.* 2023;46 (Supplement_1):S203-S215. Available at: https://diabetesjournals.org/care/issue/46/Supplement_1. Accessed on March 9, 2023.
6. Price R, Smith D, Franklin G, et al. Oral and topical treatment of painful diabetic polyneuropathy: Practice Guideline update summary. Report of the AAN Guideline Subcommittee. *Neurology*. 2022;98(1):31-43.
7. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for developing a diabetes mellitus comprehensive care plan. *Endocr Pract*. 2015;21(Suppl 1):1-87.
8. Macfarlane GJ, Kronisch C, Dean LE, et al. EULAR revised recommendations for the management of fibromyalgia. *Ann Rheum Dis*. 2017;76:e54.
9. Winkelman JW, Armstrong MJ, Allen RP, et al. Practice guideline summary: treatment of restless legs syndrome in adults. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2016;87:1-9.
10. Winkelmann J, Allen RP, Högl B, et al. Treatment of restless legs syndrome: evidence-based review and implications for clinical practice (Revised 2017). *Mov Disord*. 2018;33(7):1077-1091.
11. Garcia-Borreguero D, Silber MH, Winkelman JW, et al. Guidelines for the first-line treatment of restless legs syndrome/Willis–Ekbom disease, prevention and treatment of dopaminergic augmentation: a combined task force of the IRLSSG, EURLSSG, and the RLS-foundation. *Sleep Med*. 2016;21:1-11.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/16/2022
Annual Revision	**Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:** Addition of "between the brand and the bioequivalent generic product" to criterion regarding the use of generic prior to the brand. **Postherpetic Neuralgia:** Addition of "between the brand and the bioequivalent generic product" to criterion regarding the use of generic prior to the brand.	03/22/2023